essentially of about 1% to about 15% of propofol, up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent in an aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, the dispersion being devoid of additional bactericidal or bacteriostatic preservative agents, provided the ratio of propofol to diluent is about 1:4 to about 1:0.1, and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5, and where the dispersion has a viscosity of from about 0.8 to about 15 centipoise.

16. A method of reducing or substantially completely eliminating irritation upon injection of a formulation containing propofol comprising administering a stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm consisting essentially of about 1% to about 15% of propofol, up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent, with the aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, and the dispersion being devoid of additional bactericidal or bacteriostatic preservative agents.

17. The method of claim 16 where the ratio of propofol to diluent is about 1:4 to about 1:0.1.

18. The method of claim 16 where the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5.

19. The method of claim 16 where the dispersion has a viscosity of from about 0.8 to about 15 centipoise.

20. A method of inducing anesthesia or sedation comprising administering to a subject in need of same an anesthesia- or sedation-inducing amount of a stable, sterile, and antimicrobial injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm consisting

essentially of about 1% to about 15% of propofol, up to about 7% of a propofol soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent, with the aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, and the dispersion being devoid of additional bactericidal or bacteriostatic preservative agents, provided the ratio of propofol to diluent is about 1:4 to about 1:0.1, and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5, and the dispersion has a viscosity of from about 0.8 to about 15 centipoise.

21. A method of inducing anesthesia or sedation comprising administering to a subject in need of same an anesthesia- or sedation-inducing amount of a stable, sterile, and antimicrobial injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm consisting essentially of about 1% to about 15% of propofol, up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent, the aqueous phase comprising a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, and the dispersion being devoid of additional bactericidal or bacteriostatic preservative agents.

22. The method of claim 21 wherein the ratio of propofol to diluent is about 1:4 to about 1:0.1.

23. The method of claim 21 wherein the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5.

24. The method of claim 21 wherein the dispersion has a viscosity of from about 0.8 to about 15 centipoise.

25. The method of any of claims 15, 16, 20, and 21 where the propofol-soluble diluent is one or more selected from isopropyl myristate, cholesteryl oleate, ethyl oleate, squalene, squalane, alpha-tocopherol, and Miglyol-810.

26. The method of any of claims 15, 16, 20, and 21 where the propofol-soluble diluent is one or more selected from pharmaceutically acceptable natural triglycerides from vegetable or animal sources, pharmaceutically acceptable vegetable oils, and omega-3 polyunsaturated fish oils.

27. The method of any of claims 15, 16, 20, and 21 where the surface stabilizing amphiphilic agent is Lipoid E80, or Lipoid EPC, or Lipoid SPC, or Lipoid SPC-3, or phospholipon-90H or phospholipon-100H.

28. The method of any of claims 15, 16, 20, and 21 where the surface stabilizing amphiphilic agent is 1,2-dimristoyl-sn-glycero-3-phosphocholine, or 1,2-dimristoyl-sn-glycero-3-[phospho-rac-(1-glycerol)], or egg lecithin, or egg phosphatidylcholine, or soy phosphatidylcholine, or saturated soy phosphatidylcholine, or soy lecithin, or dimyristoylphosphatidylcholine, or dimyristoylphosphatidylglycerol.

29. The method of any of claims 15, 16, 20, and 21 where the tonicity modifier is sucrose, dextrose, trehalose, mannitol, lactose, or glycerol.

30. The method of any of claims 15, 16, 20, and 21 where the dispersion is suitable for intravenous injection.

REMARKS

Additional claims have been provided which are directed to subject matter disclosed in this application. Basis for these claims is explained in detail in the attachment to this Preliminary Amendment.

An examination on the merits is awaited taking into account the Information Disclosure Statement filed concurrently herewith. Copies of the documents referred to are of record in parent application Serial No. 09/376,487 currently pending in Art Unit 1617.